SEP 2 8 2001

Sysmex™

SYSMEX CORPORATION
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LONG GROVE, IL 60047-9596
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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K012372.

1. **Submitted By:**

Chris Stukel
Sysmex Corporation of America
Gilmer Road, 6699 RFD
Long Grove, IL 60047
1-847-726-3523 (PHONE)
1-847-726-3559 (FAX)
July 25, 2001

2. **Name of Device:**

Trade Name- Sysmex UF-50™

Common Name- Fully Automated Urine Cell Analyzer

Classification Name- Urine Particle Counter

3. **Predicate Device:**

Sysmex UF-100™

4. **Device Description:**

The UF-50 is a fully automated urine cell analyzer for urinalysis in clinical laboratories. It analyzes formed elements in urine using flow cytometry technology.

5. **Intended Use:**

The UF-50 is intended for *in vitro* diagnostic use in urinalysis in clinical laboratories. The instrument is a medical device which flags specimens containing certain abnormalities. Laboratorians are responsible for final microscopic review of abnormalities.

6. **Technology Characteristics:**

	UF-50	UF-100
Flow Cytometry detection with Argon laser beam for all parameters?	YES	YES
Flow Cytometry plus Electric impedance detection for three parameters?	NO	YES

7. **Clinical Performance Data:**

Correlation studies were performed to evaluate the equivalency of the UF-50 performance compared to the predicate device, the UF-100. The comparison results indicated equivalent performance of the two analyzers, therefore supporting the claim of substantial equivalence.

8. **Conclusions:**
The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Chris Stukel, BSMT (ASCP)
Regulatory Affairs Specialist
Sysmex Corporation
Gilmer Road
6699 RFD
Long Grove, Illinois 60047-9596

SEP 2 8 2001

Re: K012372
Trade/Device Name: Sysmex™ UF-50™
Regulation Number: 21 CFR § 864.5200
Regulation Name: Counter, Urine Particle
Regulatory Class: II
Product Code: LKM, GKZ
Dated: July 25, 2001
Received: July 26, 2001

Dear Mr. Stukel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K012372

Device Name Sysmex UF-50™

Indications for Use

The Sysmex UF-50 is a fully automated urine cell analyzer intended for *in vitro* diagnostic use in urinalysis within the clinical laboratory. The UF-50 replaces microscopic review of normal/ abnormal specimens and flags specimens containing certain abnormalities which indicate the need for further testing. Laboratorians are responsible for final microscopic review of flagged abnormalities.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012372

Prescription Use ✓ OR Over-The-Counter Use ____